Are Public Health Decisions Based on Inaccurate COVID Tests?

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Story at-a-glance

- Multiple stories are reaching the news of people who are testing both positive and negative for COVID-19, revealing the tests' lack of reliability
- Employers and doctors are making decisions based on test results. Some data suggest that testing after symptoms are evident will produce more accurate results
- Abbott Labs ID NOW point-of-care test that takes five to 13 minutes for results, has a high inaccuracy rate, leading some hospitals to decline its use
- Confusing sets of data are feeding public fears and being used in the efforts for global surveillance that will likely include digital identification to track and monitor people

Disease screening and testing are among the most basic tools in public health and preventive medicine. Women receiving prenatal care undergo a variety of tests to protect the health of their unborn child. Newborn children are tested for inborn errors in metabolism so that early intervention may reduce the risk of damage.

Adults are screened for cardiovascular disease while influenza testing helps determine the spread of infectious disease during flu season. Inadequate testing for COVID-19 during its early months has been blamed for widespread transmission.

Early testing potentially could have helped contain the virus without the need for extensive shutdowns. Soon after China announced it identified a novel coronavirus, German scientists developed the first diagnostic test. By February 2020, the World Health Organization had shipped 250,000 tests around the world to 159 laboratories.[1,2]

However, instead of using the WHO test, the U.S. CDC and FDA decided to create their

own. During past outbreaks of Ebola and Zika, the U.S. made similar moves. William Schaffner, an adviser to the CDC and an infectious disease specialist at Vanderbilt University, spoke to a reporter from Business Insider:[3]

> *"The notion of accepting a test developed by someone else I think was a bit alien. There may have been other considerations of which I'm not aware, but I'm sure that pride was one of them: 'We know how to do this, thank you very much. We'll develop our own.'"*

In other words, pride may well have stood in the way of U.S. officials distributing early testing. February 6 and 7, the CDC shipped a mere 90 test kits to state-run labs public health labs and by February 12th problems with those tests were announced. At the end of February 2020, the planned use for the tests was only on "symptomatic patients with a travel history."

The FDA waited until February 29, 2020, before it released academic hospital labs to develop testing. In a country with more than 330 million individuals,[4] enough tests for 1.5 million were shipped on March 4, 2020. Yet, despite the number of, or lack of, testing kits, the decisions being made can only be as successful as the accuracy of the test.

Inaccurate Tests Raise Public Health Risks

Multiple stories are being told of individuals who have received false positive or false negative tests. NBC News tells the story of Sarah Bowen, a 31-year-old therapy consultant from Portland, Oregon.[5] She is employed at a doctor's office and her trouble began with a sore throat.

The next day she felt significantly worse and was able to get a test for COVID-19. When the results came back negative, her doctor thought the symptoms were related to allergies or a different type of virus. Bowen reported she started to get short of breath and her symptoms continued to get worse.

She took another test, and again it came back negative. Despite her symptoms, which were consistent with COVID-19, her doctor did not believe she had the novel coronavirus. At the time of the report at the end of May 2020, Bowen's diagnosis was still unclear.

For Danielle Fried, whose story is told in The Wall Street Journal,[6] her positive test sent her into quarantine until her symptoms subsided. Not long after, her antibody test came back positive indicating her infection was inactive.

To return to her job she was required to get another test, which was positive for an active COVID-19 infection, which required another two-week quarantine. Yet, it isn't clear if she had another infection or if the test was a false positive.

Contradictory tests are not unusual as Zalman Goldstein has found after six COVID-19 tests showed three positive and three negatives. Two were taken on the same day and

came back with conflicting results.

Goldstein is 74 years old and needs a medical procedure to address a kidney illness. The hospital requires a negative test before proceeding, yet with each test, Goldstein's results are contradictory.

Timing Your Test May Be Important

Test results may be unreliable or inconsistent when samples are taken too early or late during the disease. Robert Wachter, chairman of the department of medicine at the University of California, spoke with a reporter from The Wall Street Journal, saying: "Situations like this are occurring with distressing frequency and are confusing to patients and their doctors."[7]

He went on to explain that the tests may show inaccurate results if a person is tested too early in the disease. Yet, as Stephanie Zeidenweber discovered, her tests for COVID-19 — taken within days of her first symptom and weeks later — were both negative.

Later, she took two antibody tests on the same day to determine if she had been infected with SARS-CoV-2. One came back negative and the other was positive. Dr. Alan Wells from the University of Pittsburgh Medical Center believes some false negatives are due to how the specimens are collected and not the tests themselves. He explained to NBC News:[8]

> *"You're sampling blindly. You're hoping you get the right spot. Then as the disease progresses, the virus might migrate down into your lungs. You have to be at the right place at the right time."*

A second type of test collects saliva in a test tube where it's evaluated in a lab. Wells said the results of these tests may be worse, explaining pharyngeal swabs are used to test tissue where the virus is known to replicate.

Saliva tests may be missing up to 50% of asymptomatic positive cases. Using a literature review and a pooled analysis of seven studies, one team found that proper timing of the test was also essential. The results showed a probability of 100% false negative on day one, which fell to 67% by day 4.[9]

PCR Testing Isn't Accurate for Active Infections

However, even when samples are taken at the ideal time, the results can still be incorrect. An article in the Mayo Clinic proceedings criticized public health reliance on polymerase chain reaction (PCR) testing. To illustrate the point, the authors of the paper wrote:[10]

> *"To illustrate the potential magnitude of this problem in the general population, consider the following examples from Spain and the United States, assuming a test with 90% sensitivity.*

> *The president of the region of Madrid has predicted that 80% of Madrid's 6.5 million residents will become infected by COVID-19. If the entire population was tested, of the anticipated 5.2 million infected individuals, 520,000 people would be falsely classified as free of infection."*

One of the problems with getting false negatives, as Wells points out, is that you "create a false sense of security."[11] Dr. Priya Sampathkumar is an infectious disease specialist at Mayo Clinic and one of the authors of the paper. She commented:[12]

> *"RT-PCR testing is most useful when it is positive. It is less useful in ruling out COVID-19. A negative test often does not mean the person does not have the disease, and test results need to be considered in the context of patient characteristics and exposure."*

As I've described before, the PCR test traces genetic material of the virus that may be from a dead cell or from a live virus. Scientists are finding the SARS-CoV-2 virus leaves dead fragments that can take months to clear after an infection.[13] This can lead to a number of false positives of an active infection.

Some Hospitals Decide ID NOW Tests Ineffective

Abbott Labs developed another type of diagnostic test that produces results in five to 13 minutes. Called the ID NOW point-of-care test, it uses a method that is different from PCR.[14] The Abbott test kit uses isothermal nucleic acid amplification, which was found to potentially return nearly 50% false negatives, according to the authors of one study from New York University[15] and as reported by NBC News.

May 14, 2020, the FDA issued an alert that data from the Abbott test may return false negative results.[16] Although they said the test could still be used, negative results should be confirmed with an additional test. In response to this, the FDA reported "Abbott has agreed to conduct post-market studies for the ID NOW device that each will include at least 150 COVID-19 positive patients in a variety of clinical settings."[17]

May 21, 2020, Abbott published a press release in which they reported results from three separate Abbott Labs sponsored studies. The results of one showed that an "Urgent care clinic study shows ID NOW test performance of ≥94.7% positive agreement (sensitivity) and ≥98.6% negative agreement (specificity) compared to lab-based PCR reference tests."[18]

Most importantly, Abbott stated the full results of these studies and analysis are not yet complete. Until the data are released, it's difficult to determine whether the results are accurate. Some hospitals aren't convinced the results are accurate or they may not want to use the test altogether, when a second is required to confirm a negative test.

An NBC News reporter called 10 U.S. medical facilities and found that seven were not using the test. Each cited accuracy as the reason, including Vanderbilt University Medical Center, whose representative told the NBC reporter, "No patient at Vanderbilt University Medical Center has been tested via the Abbott ID NOW rapid test. Here, there were concerns about the sensitivity of that test."[19]

As demonstrated in previous studies, industry funding can exaggerate outcomes. Researchers have found this to be true in several industries.[20] The authors of a paper published in Jama Network came to the conclusion that:[21]

> *"Although industry sponsorship of clinical trials can lead to important therapeutic advances, the potential for bias in these studies may exist on multiple levels … By establishing checks and balances for academic-industry partnerships, such proposals may help to mitigate the potential for bias in industry-sponsored research."*

Confusing Data Feed Fear Without Science

Without accurate testing data, large corporations and the media can continue to feed public fear. As I've written about in the past, one of the key players in this process is a man without any medical education whose sole qualification appears to be that he's a billionaire.

Bill Gates has proposed plans that go far beyond mandating a vaccine: His proposal includes digital surveillance to track and monitor people, riding on the coattails of COVID-19. Once in place, global disease surveillance systems will be next to impossible to dismantle and will naturally transition into other functions under the auspices of creating a world where disease can be tracked to improve health. And who doesn't want a healthy world?

There is also every reason to believe a digital tracking system this intricate will be combined with digital identification and an economic system to enforce compliance. In my series on Bill Gates linked below, I outline some of the steps currently being taken to quietly and surreptitiously go after a surveillance regime monitored and run by organizations with their financial future in mind.

In the past, behavior could change under the threat of war or terrorism. The current acts of terrorism that trigger behavior change are identity fraud and infectious diseases. The Gates Foundation has direct ties to funding the World Health Organization as well as other groups that shape decisions in the U.K. and the U.S.

This is a moment in history when we will look back and recognize it was a time in which decisions were made that protected or exposed our personal rights and public health. The role of government does not include creating mandates that eliminate personal decision making with regard to vaccination, medical testing and autonomy. It is your right and responsibility to take control of your health.

Giving control to government or large organizations will eventually strip people of their personal freedoms, with devastating consequences. I encourage you to get educated on the decisions being made “for” you and learn how you can make a difference for yourself and your community.